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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,027

Applicant(s)

BURBANK ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30, 32-38, 40-54 and 56-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-30, 32, 33, 35-38, 40-47 and 62 is/are allowed.
- 6) ☒ Claim(s) 34, 48, 63 and 64 is/are rejected.
- 7) ☒ Claim(s) 49-54 and 56-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10112005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed January 23, 2006. The Examiner acknowledges the amendments to claims 28, 34, 48, 51, 61 and 62, as well as the addition of New claims 63 and 64. Claims 28-30, 32-38, 40-54 and 56-64 are pending.

Drawings

2. The drawings were received on January 23, 2006. These drawings are acceptable.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second tissue cutting element disposed over at least the apex portion of a conical stylet head that has an outer diameter larger greater than an inner diameter of the open distal end of the elongate cannula must be shown or the features canceled from claim 34. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 48, 58 and 63 are objected to because of the following informalities:
 - a. At claim 48, line 4, the limitation "and a longitudinal axis" at line 4 is redundant in view of the limitations recited at line 2 of the claim. Therefore, the limitation at line 4 should be deleted.
 - b. At claim 58, line 5, "[[a]]" should be deleted.
 - c. At claim 63, line 12, "which" apparently should read --that--.Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention.

While the original disclosure provides support for a stylet having a conical head with an insulative frustum-shaped base portion and an apex portion forming the second tissue cutting element that is spaced away from the shaft by an insulative base portion (see page 8, lines 18-25 and Figure 16), the original disclosure does not appear to provide support for an elongate stylet with such a stylet head configuration where the distal portion of the stylet has an outer diameter that is greater than an inner diameter of the open distal end of the elongate cannula and where the second tissue cutting surface of a second tissue cutting element is *disposed over* at least the apex portion and lies in a plane parallel with the longitudinal axis as claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 34, 63 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 34, it is unclear how the apex portion of a conical element can be said to lie in a plane perpendicular to the longitudinal axis of a stylet.

Regarding claim 63, at lines 6-9, the claim language is unclear as to whether the stylet or the cannula is configured for axial translation, has a tissue penetrating distal end, and an outer diameter greater than a diameter of the electrosurgical cutting element.

Claim 63 recites the limitation "the electrosurgical cutting element" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Further regarding claim 63, at lines 12-14, the claim language is unclear as to what lies in a plane traversing the longitudinal axis of the cannula.

Further regarding claim 63, it is unclear whether or not the claim is complete since the claim ends in a semicolon rather than a period.

Claim 64 recites the limitation "the tissue penetrating distal tip" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 48 is rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al. ('955).

Bryan et al. teach a biopsy apparatus including an elongate cannula (24) having a longitudinal axis, an open distal end, a proximal end, an inner lumen extending to and in fluid communication with the open distal end and a longitudinal axis; a first tissue cutting element (50) disposed on the open distal end of the cannula lying in a plane traversing the longitudinal axis of the cannula and having a transverse dimension; an elongate stylet (16) which is slidably disposed in part within the inner lumen of the cannula, which is configured for axial translation between a withdrawn position and an extended position and which has a distal end (13) configured (at 52)

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to receive the first tissue cutting element; and a second tissue cutting element (see at least Figures 3, 6, 12, 14 and 15) which is disposed on a distal end (13) of the stylet distal to the first tissue cutting element and which lies in a plane parallel with the longitudinal axis of said stylet and which has a cutting surface with at least one transverse dimension (measured from one side of the stylet head at the base of the cutting edge distally to the distal tip and proximally to a the base of the cutting edges at a diametrically opposite side of the stylet head) which is larger than at least one transverse dimension of the first tissue cutting element (see Figure 12).

11. Claim 63 is rejected under 35 U.S.C. 102(b) as being anticipated by Rydell ('659).

Rydell teaches a biopsy device with an elongate cannula (12) which has a longitudinal axis, an open distal end, a proximal end and an inner lumen (18) extending to and in fluid communication with the open distal end; an elongate stylet (36) which is disposed at least in part within the inner lumen of the cannula, which is configured for axial translation between a withdrawn position and an extended position and which has a tissue penetrating distal end (44) and which has an outer diameter that is greater than a diameter of the electrosurgical cutting element; and an electrosurgical tissue cutting element (32) at the open distal end of the cannula which is configured to sever a tissue specimen surrounding a portion of the elongated stylet which extends out of the cannula in the extended position and which lies in a plane traversing the longitudinal axis of the cannula.

Allowable Subject Matter

12. Claims 28-30, 32, 33, 35-38, 40-47 and 62 are allowed over the prior art of record.

13. Claims 49-54, 56 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 58-61 would be allowable if rewritten to overcome the objection to claim 58 set forth in this Office action.

15. Claims 34 and 64 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

16. Applicant's arguments, see page 11 of the Remarks, filed January 23, 2006, with respect to the rejection of claims 61 and 62 under 35 U.S.C. 112, first paragraph, and the rejection of claims 28-30, 32, 33, 35-38, 40 and 41 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejections of claims 28-30, 32, 33, 35-38, 40, 41, 61 and 62 have been withdrawn.

17. Applicant's arguments filed January 23, 2006 have been fully considered but they are not persuasive.

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Regarding the rejection of claim 34 under 35 U.S.C. 112, second paragraph, Applicant contends that the amendments to the claim should resolve these issues. The Examiner respectfully disagrees. Several problems with respect to 35 U.S.C. 112 exist in claim 34 as described in detail above.

Regarding the rejection of claim 48 under 35 U.S.C. 102(e) as being anticipated by Bryan et al, Applicant contends that Bryant et al. do not teach or suggest a second tissue cutting member with a cutting surface having at least one transverse dimension which is larger than at least one transverse dimension of the first tissue cutting element. Applicant further contends that the cutting surfaces of the device described in the Bryan et al. reference are smaller in transverse dimensions than the first cutting member. The Examiner respectfully disagrees. The claim language does not require that the transverse dimension of cutting surface be measured strictly as perpendicular with respect to the longitudinal axis of the stylet or cannula. Broadly interpreted, the limitation a "transverse dimension" only requires a dimension that crosses the longitudinal axis. Therefore, the length of the cutting surface, as illustrated in Figure 12 of the Bryan et al. reference, when measured from one side of the stylet head at the base of the cutting edge distally to the distal tip and proximally to the base of the cutting edge at a diametrically opposite side of the stylet head can be considered to be a transverse dimension which is larger than the transverse dimension (measured as perpendicular to the longitudinal axis) of the first tissue cutting element. In view of the foregoing, the rejection of claim 48 under 35 U.S.C. 102(e) as being anticipated by Bryan et al. is maintained.

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Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
April 11, 2006